K991862

JAN 13 2000

510(k) Summary

Company: Schafer Micomed GmbH
Sparweiser Weg 4
73035 Goppingen, Germany
Phone: +49 71 61 94 96 43 Fax: +49 71 61 94 96 46

Tradename: Micomed Posterior Doublerod System

Classification: Class II

Description: The Micomed Posterior Doublerod System is a low profile, top-loading spinal fixation system available in titanium. The system consists of pedicle screws of varying lengths and diameters, open and closed hooks, and fluted and threaded rods. A set of instruments is available for use with the Micomed Posterior Doublerod System.

Material: The components of the Micomed Posterior Doublerod System are manufactured from titanium in conformance with ASTM F136.

Indications: The Micomed Posterior Doublerod System is a pedicle screw system indicated for treatment of severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The Micomed Posterior Doublerod System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and falled previous fusion (pseudoarthrosis).

When used as a non-pedicle screw fixation system, the Micomed Posterior Doublerod System is also intended for scoliotic, lordotic, or kyphotic deformities such as scoliosis, Scheuermann's disease); degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, and fractures of the posterior thoracolumbar spine from levels T4 to S1.

Performance Data: The Micomed Posterior Doublerod System has been shown to have acceptable biomechanical behavior when compared to TSRH (Sofamor Danek), VSP (AcroMed), ISOLA (AcroMed), AcroMed Pedicle Screw (AcroMed) Dyna-Lok (Danek) and Miami Moss (DePuy Motech).

Substantial Equivalence: The Micomed Posterior Doublerod System is substantially equivalent to TSRH (Sofamor Danek), VSP (AcroMed), ISOLA (AcroMed), AcroMed Pedicle Screw (AcroMed) Dyna-Lok (Danek) and Miami Moss (DePuy Motech).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2000

Ms. Charmaine Henderson
Consultant to Shäfer Micomed, GmbH
511 Catalina Road
Fullerton, California 92835

Re: K991862
Trade Name: Micomed Posterior Doublerod System (MPDS)
Regulatory Class: II
Product Code: MNI, MNH and KWP
Dated: December 2, 1999
Received: December 6, 1999

Dear Ms. Henderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991862

2000

INDICATIONS FOR USE ENCLOSURE

510k: K991862

Device: Micomed Posterior Doublerod System

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Russell Sayer for TLP
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991862

X Prescription use _Over the Counter Use